SPD Employee Continuing Education

Training Guide

1010. Regulatory and Recommending Agencies Governing SPD Activities

Prepared by the SPD Advisory Group
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OBJECTIVES:

Upon completion of this training, the participants will be able to:

1) Identify some of the governing bodies that affect SPD activities.
2) Briefly describe the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
3) Identify one of the main JCAHO standards relating to SPD.
4) Discuss the highlights of Occupational Safety and Health Administration (OSHA) Blood borne Pathogens Standard.
5) Discuss the highlights of OSHA's Medical Surveillance guidelines for ethylene oxide.
6) Explain the association between SPD and the Association for Professionals in Infection Control and Epidemiology (APIC).
7) Explain some of the Environmental Protection Agency's (EPA) recommendations for the use of Ethylene Oxide (EtO) as a sterilant in healthcare facilities.
8) Describe the activities of The Association for the Advancement of Medical Instrumentation (AAMI).
9) Discuss the two roles that the Food and Drug Administration (FDA) plays in the SPD program.
10) Describe the role the Certification Board for Sterile Processing and Distribution (CBSPD) plays in the SPD department.

INTRODUCTION:

SPD activities cover a wide range of functions, therefore, regulations and recommended practices come from many directions. Some of the better known regulating and recommending agencies are:

1) Occupational Safety and Health Administration (OSHA)
2) Environmental Protection Agency (EPA)
3) Food and Drug Administration (FDA)
4) The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
5) American Society for Healthcare Central Service Professionals (ASHCSP)
6) The Association for the Advancement of Medical Instrumentation (AAMI)
7) Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)

The **Occupational Safety and Health Administration (OSHA)** is a federal agency that protects workers from occupationally-caused illnesses and work related injuries. OSHA's Bloodborne Pathogens Standard (1910.1030) applies to all occupational exposure to blood or other potentially infectious materials. The standard provides guidance in areas such as exposure control and communication of hazards to employees. It also identifies the methods of compliance a healthcare facility should utilize, including engineering controls, personal protective equipment, housekeeping controls, and regulated waste containment. The OSHA Bloodborne Pathogens Standard also provided for the Hepatitis B vaccination to be available to all employees who have the potential for occupational exposure. In addition, the standard provides for warning labels and signs or red bags/red containers to be used when dealing with blood or other potentially infectious material. The standard also requires all facilities to evaluate and institute engineer controls to protect workers. These controls include sharps disposal containers, self-sheathing needles and syringes, and needleless systems. Finally, according to the standard, employers will ensure that all employees with occupational exposure participate in a training program at no cost to them during working hours.

OSHA's Medical surveillance guidelines for ethylene oxide (1910.1047) particularly apply to SPD through the medical surveillance program. SPD employees must be given a base line physical that includes medical history, physical exam, blood work and respiratory function tests. In the event of an exposure of ethylene oxide, the employee is medically evaluated to determine any changes of the baseline physical. This retesting is only required annually if the employee is exposed at or above the action level, for 30 or more days of the year, or if an employee feels they are suffering from ethylene oxide exposure.

OSHA requires all facilities to have a **Hazardous Communication Program.** This program includes the use of Material Safety Data Sheets (MSDS) as well as proper labeling of hazardous materials. Part of the Hazardous Communication program is annual training, and up to date documentation of MSDS's on chemicals used in all areas of the Medical Center. (The web site for OSHA is www.osha.gov)

The **Environmental Protection Agency (EPA)** is an agency that enforces the federal laws that relate to the air, water and the environment. The EPA has published recommendations for modifications in workplace design and practice in hospitals and healthcare facilities for which the EPA has registered Ethylene Oxide (EtO) for use as a sterilant. These recommendations are intended to help reduce the exposure of hospital and healthcare workers to EtO to 1ppm (part per million).

Some workplace design recommendations include:

1) Installation of "capture boxes" (a piece of equipment that totally encloses the floor drain where the discharge from the sterilizer is pumped);
2) Ventilation of aeration units;
3) Ventilation of sterilizer door area;
4) Installation of alarm systems for EtO monitoring.

Workplace practice recommendations include:

1) Identification of door opening procedures on sterilizers with purge cycles versus sterilizers without purge cycles;
2) Specific chamber unloading procedures;
3) Maintenance procedures.

(The web site for EPA is www.EPA.gov)

The **Food and Drug Administration (FDA)** is an agency of the U.S. Department of Health and Human Services that is responsible for protecting the public from hazardous drugs and food products. The FDA also gives guidance in the tracking of medical devices as well as releasing announcements of recalled medical items, drugs and food products. It has released guidance on the reprocessing and reuse of Single-use devices on August 14,2000. VA policy mandates that single use items will not be reprocessed.. (The FDA's web site is www.fda.gov)

The **Joint Commission on Accreditation of Healthcare Organizations (JCAHO)** standards addresses a healthcare organization's level of performance in specific areas—not just what the organization is capable of doing, but what it actually does. Healthcare organizations pay JCAHO to send surveyors to their facilities on unannounced visits in order to receive Joint Commission Accreditation for their facilities. Surveyors will evaluate the organization's compliance against all applicable standards for that accreditation program and the population served. An organization's scope of services defines which standards apply.

Some of the Joint Commission's standards are: Improving Organization Performance, Leadership, Management of Human Resources, and Surveillance, Prevention, and Control of Infection. The standard most closely affecting SPD activities is Surveillance, Prevention, and Control of Infection. The goal of this standard is to identify and reduce the risks of acquiring and transmitting infections. Some points the surveyors would be scoring are:

1) The organization uses a coordinated process to reduce the risks of endemic (common cause) and epidemic (special cause) nosocomial infections in patients and healthcare workers;
2) The infection control process is managed by qualified individuals;
3) The hospital takes action to prevent or reduce the risk of nosocomial infections in patients, employees, and visitors;
4) Management systems support the infection control process.

Specific to SPD activities within this standard, the surveyors would look for policies and procedures in each department performing decontamination and sterilization activities. The policies and procedures should be consistent in intent and application throughout the hospital, related to the following nine elements:

1) The receiving, decontaminating, cleaning, preparing, and disinfecting or sterilizing of reusable items;
2) The assembly, wrapping, storage, distribution, and quality control of sterile equipment and medical supplies;
3) The use of sterilization process monitors, including temperature and pressure recordings, and the frequent use of appropriate chemical indicators or bacteriological spore tests for all sterilizers;
4) Processes designed to provide for the continued sterility of hospital-sterilized and commercially prepared items through appropriate packaging, storage, and other methods to provide for package integrity;
5) The designation of time-related or event-related shelf life for hospital-sterilized medical items;
6) The designation of time-related or event-related shelf life for commercially prepared items that do not have a specific expiration date and are labeled by the manufacturer as being sterile;
7) A process that provides for recall and disposal or reprocessing of outdated sterile supplies, if a time-related designation is used;
8) Emergency collection and disposition of supplies when recalls have been issued by the manufacturer or appropriate governmental agencies, or where warranted by the hospital's quality control or assurance process;
9) A process that provides for timely notification of the attending physician and members of the hospital's risk management program of any emergency collection of supplies.

The **American Society for Healthcare Central Service Professionals** is a professional organization that promotes effective health care utilization of central service, sterile processing and inventory management practices through education, professional and organization development. The ASHCSP has available recommended practices for all aspects of central service and their activities. (The web site for ASHCSP is www.hospitalconnect.com/ashcsp)

The **Association for the Advancement of Medical Instrumentation (AAMI)**. An alliance of engineering, medicine, nursing, industry, and government professionals united by the common goal of increasing the understanding and beneficial use of medical instrumentation. AAMI is widely recognized as one of the principal voluntary standards organizations in the United States.

A voluntary ***standard*** for a medical device recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria, and measurement techniques.

A ***recommended practice*** contains guidelines for the use, care, and processing of a medical device or system. It describes procedures and practices that will help ensure that a device is used safely and effectively and that its performance is maintained.

All AAMI standards and recommended practices are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary standards and recommended practices are adopted by government regulatory agencies. Nevertheless, a standard or recommended practice is truly useful only when it is relied on in conjunction with other sources of information and policy guidance, knowledge about specific situations, and a framework of professional experience. (The web site for AAMI is www.aami.org)

The **Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)**, provides for an organized, systematic approach to the control of nosocomial infections. APIC is a multi-disciplinary, voluntary, international organization. Its purpose is to influence, support, and improve the quality of healthcare through the practice and management of infection control and the application of Epidemiology in all health care settings. APIC develops recommendations, many which are used in JCAHO standards. Many of the recommendations are directed toward disinfection, sterilization, and antisepsis. (The web site for APIC is www.apic)

REGULATORY AND RECOMMENDING AGENCIES
GOVERNING SPD ACTIVITIES
POST-TEST

1. JCAHO stands for: _____ _____ _____ _____ _____.

2. The JCAHO standard most closely affecting SPD activities is:
   a. Improving Organization Performance
   b. Leadership
   c. Management of Human Resources
   d. Surveillance, Prevention, and Control of Infection

3. JCAHO surveyors come to healthcare facilities _____.

4. The BloodBorne Pathogens Standard is a _____ standard.
   a. JCAHO
   b. OSHA
   c. EPA
   d. AAMI

5. The use of Ethylene Oxide is regulated by the _____ _____ _____.

6. The EPA provided for the Hepatitis B vaccination to be available to employees with the potential for occupational exposure.

   TRUE FALSE

7. OSHA's Bloodborne Pathogens Standard provides guidance in areas such as exposure control and communication of hazards to employees.
   TRUE FALSE

8. AAMI is a unique alliance of physicians, surgeons, and nurses.
   TRUE FALSE

9. The Association for the Advancement of Medical Instrumentation is a recommending agency versus a regulatory agency.
   TRUE FALSE

10. A recommended practice by AAMI is:
   a. Recommends to the manufacturer information that should be provided
   b. Contains guidelines for the use, care, and processing of a medical device or system.
   c. Both of the above
   d. Neither of the above

ANSWERS TO POST-TEST

1. Joint Commission on Accreditation of Healthcare Organizations
2. d
3. Unannounced
4. b
5. Environmental Protection Agency
6. False
7. True
8. False
9. True
10. b

References:

1. www.hospitalconnect.com/ashcsp/aboutashcspindex.html
2. www.ssha.gov/pls/oshaweb
3. www.aami.org
4. www.apic.org
5. www.fda.gov/cdrh/reuse/reuse-documents.html